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| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10 | FEI: 3004557352 | Other FDA Registrations: Blood: Devices: Drugs: | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2022 Last Registration Receipt Date: 12/02/2021 Summary Report Print Date: 12/15/2021 |
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| Legal Name and Location: We Are Sharing Hope SC 164 Lott Court W. Columbia, South Carolina 29169 USA Phone: 843-763-7755 Ext.: | Reporting Official: Lorraine Kemp, Director Quality Systems 3950 Faber Place Drive Suite 400 Charleston, South Carolina 29405 USA Phone: 843-725-5526 Ext. kempl@sharinghopesc.org | Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 3003935893 Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). |
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| HCT/P(s) | Donor Type(s) | Establishment Functions | | | | | | | | Date of Discontinuance | Date of Resumption | Proprietary Name(s) |
|-------------------------------------|---------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|------------------------|--------------------|---------------------|
| | | Recover | Screen | Donor Testing | Package | Process | Store | Label | Distribute | | | |
| Amniotic Membrane | | | | | | | | | | | | |
| Blood Vessel | | X | X | X | X | | | | X | | | |
| Bone | | X | X | X | X | | | | X | | | |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | X | X | X | X | | | | X | | | |
| Cornea | | | | | | | | | | | | |
| Dura Mater | | X | X | | X | | | | X | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | X | X | X | X | | | | X | | | |
| Heart Valve | | X | X | X | X | | | | X | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | X | X | X | X | | | | X | | | |
| Nerve Tissue | | | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | X | X | X | X | | | | X | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | | | | | | | | | |
| Semen | | | | | | | | | | | | |
| Skin | | X | X | X | X | | | | X | | | |
| Tendon | | X | X | X | X | | | | X | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3004557352

Legal Name:

We Are Sharing Hope SC